510(k) Summary

JUN - 8 2007

Submitter Name: Submitter Address:	Cardio Life Research s.a. Rue de Clairvaux 40/203 B1348 Louvain la Neuve Belgium
Phone Number: Fax Number:	011 32 10 480 490 011 32 10 456 926
Contact Person:	Michel Joie
Date Prepared:	31 January 2007
Device Trade Name:	Portaclamp® Flex
Common Name	Aortic Clamp
Classification Name, Number & Product Code:	Clamp, Vascular 870.4450 DXC
Predicate Devices:	Portaclamp®, Cosgrove Vascular Clamp
Device Description and Statement of Intended Use	The Portaclamp® Flex is an aortic clamping device composed of a detachable, reusable handle and a single-use, disposable clamp. It is designed to be used through a standard thoracic port to clamp the aorta during minimally invasive cardiac bypass procedures. The Portaclamp Flex consists of a flexible guide wire, two jaws that are passed over the guide wire and positioned on each side of the aorta, and a mandrel that is slid along the length of the jaws to compress the jaws and clamp the aorta. The Portaclamp® Flex is indicated to clamp the aorta during minimally invasive cardiac surgery implying the usage of an extra-corporeal circulation.
Summary of Technological Characteristics	The Portaclamp® Flex system consists of two separate flexible jaws to be positioned on either side of the aorta with the help of a supplied flexible and straight guidewire, and a sliding metallic mandrel integrating a manual grip to secure the jaws. The sliding mandrel consists of 2 detachable elements, it is delivered separately from the jaws and guide wire, and it is reusable.

A table comparing the Portaclamp® Flex to the predicate devices is attached.

Conclusion

The information discussed above demonstrates that Portaclamp® Flex is as safe, as effective, and performs as well as or better than the predicate devices.

Declarations

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any puffery or unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.

This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	Portaclamp Flex	Portaclamp	Cosgrove Vascular Clamp
510(k) Number		K033085	K974769
Manufacturer	Cardio Life Research	Cardio Life Research	Allegiance Healthcare Corp.
Classification # & Product Code	870.4450 DXC	870.4450 DXC	870.4450 DXC
Intended Use	Temporary clamping of aorta during minimally invasive endoscopic cardiac surgery implying the usage of an extra-corporeal circulation	Temporary clamping of aorta during minimally invasive endoscopic cardiac surgery implying the usage of an extra-corporeal circulation	Temporary occlusion of blood vessels during pulmonary and gastrointestinal procedures, peripheral clamping, minimally invasive and standard open cardiovascular and cardiothoracic procedures such as occlusion of the aorta and vena cava, cross clamping of the aorta, etc.
Mode of Action	Flexible jaws with rigid distal portion applied around aorta using guidewire and closed with a sliding mandrel that can be removed after clamping and reattached as needed. Proximal portion of jaws can de bent out of way.	Rigid jaws applied around aorta using guidewire and closed with an integral sliding mandrel	Jaws applied around aorta at the end of a flexible shaft which can be bent out of way.
Reusable	Clamps – No Mandrel - Yes	No	Yes
Method of Clamp Introduction	Through thoracic port during minimally invasive endoscopic procedure	Through thoracic port during minimally invasive endoscopic procedure	Through standard open or minimally invasive incision
Method of occlusion	Clamp jaws around vessel	Clamp jaws around vessel	Clamp jaws around vessel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2007

Cardio Life Research
c/o Mr. William Greenrose
President, Qserve America, Inc.
220 River Road
Claremont, NH 03743

Re: K070380
Portaclamp® Flex
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (Two)
Product Code: DXC
Dated: May 29, 2007
Received: May 31, 2007

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.1 Indications for Use Statement

510(k) Number (if known): K070380

Device Name: Portaclamp® Flex

Indications for Use:

The Portaclamp® Flex is indicated to clamp the aorta during minimally invasive cardiac surgery implying the usage of an extra-corporeal circulation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	OR	Over-The-Counter Use
X		

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070380